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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,190	06/19/2006	Anton Horn	074060.5	7416
27805	7590	11/24/2009	EXAMINER	
THOMPSON HINE L.L.P. Intellectual Property Group P.O. BOX 8801 DAYTON, OH 45401-8801			TURK, NEIL N	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/564,190

## Applicant(s)

HORN ET AL.

## Examiner

NEIL TURK

## Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 14-16, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14-16, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/9/06 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ ~~Notes of Informal Patent Application~~
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Remarks**

This Office Action fully acknowledges Applicant's remarks filed on August 28<sup>th</sup>, 2009. Claims 1-10, 14-16, 18, and 19 are pending. Claims 11-13 and 17 have been cancelled. Claim 19 is newly added herein.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the apparatus having at least one surface region and an interior region, in which the at least one surface region is an open-pore three dimensional network must be shown or the features cancelled from the claim(s). Further, the molded part being at least one of a pipette tip, microtitration plate, piece of flexible tubing, rod, single or multiple vessel, immersed body sphere or plate must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 14-16, 18, and 19** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The steps involved in the analyzing or preparing are unclearly recited. What steps are undergone to prepare a biological substance? Additionally, how does one analyze a biological substance only given the recitation to a molded plastic material with at least one surface region being an open-pore three dimensional network? The amended recitation of, "...and wherein the substance is analyzed by contacting the substance with at least one reactant bound to at least a portion of the integral molded part" does not provide any sort of analysis. Such a step only amounts to a step of "contacting" the substance with at least one reactant bound to at least a portion of the integral molded part. Further, the reactant is not even related in any way for meaningful interaction with the substance. Additionally,

with regard to dependent claims 15 and 16, what steps are involved so as to identify and quantify the analyte (cl. 15), and then further determine a specific concentration of the analyte (cl. 16)?

Additionally, what steps are involved in the preparation so as to enrich, deplete, or modify an analyte (cl. 19), and further, specifically remove at least one of a phosphate, sugar, or fatty acid moiety from the sample (cl. 18)?

Applicant's specification does not provide clear and distinct description for the processes as claimed in claims 14-16, 18, and 19 and only generally discusses uses in paragraph [0040] of the pre-grant publication US 2006/0275176.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-10, 14, and 19** are rejected under 35 U.S.C. 102(b) as being anticipated by Shukla et al. (6,416,716), hereafter Shukla.

Shukla discloses a sample preparation device with embedded separation medium (abstract). Shukla discloses a tube 1 with particles of a separation medium 4 (open-pore three dimensional network, where such separation medium defines the surface region) embedded on the inner surface of the tube (molded integrally with the plastic tube). The interior region is said to be the region of the tube where the particles

of a separation medium do not exist (lines 40-67, col. 4, fig. 1). Shukla discloses that the tube can be made of polysulfone, among others (line 66, col. 5 – line 9, col. 6). Shukla discloses that the particles of the separation medium can be porous chromatography materials, active charcoal, and affinity chromatography materials (affinity ligands bound to the surface, also providing to modify an analyte), among others (lines 1-10, col. 7). Shukla discloses that the invention can be used for the preparation of such samples as biological samples, protein containing samples, nucleic acid containing samples, and lipid containing samples, among others (lines 15-24, col. 9).

**The Office has interpreted claims 8-10** as a product-by-process claims, since a product-by-process claims is one in which the structural scope of the product is defined at least in part in terms of the method or process by which it is made. In this case, the end product is defined by the following steps: partially dissolving the plastic material on at least a part of the at least one surface region (and chemically activating the surface region, as in claim 9). Applicant is reminded that the product-by-process claim is always to a product. The reference need only to substantially meet the structure of the end product. As set forth above, the disclosure of Shukla meets the structural requirements of the end product of the integral molded part of a plastic material having at least one surface region and an interior region, in which the at least one surface region is an open-pore three-dimensional network as set forth in the instant claims. Please note that an argument that the applied reference fails to meet all claimed process/limitations of making the end product does not overcome a proper 102/103

rejection because the reference need only to substantially meet all the structure of the end product, see MPEP 2113[R-1] and *In re Fessmann*, 489 F.2d 742, 744 180 USPQ 324, 326 (CCPA 1974).

### ***Response to Arguments***

Applicant's arguments filed August 28<sup>th</sup>, 2009 have been fully considered but they are not persuasive.

**With regards to claims 14-18** rejected under 35 USC 112, 2<sup>nd</sup> paragraph, Applicant traverses the rejection. Applicant argues that claim 14 has been amended to clarify the process. Examiner argues that the amended recitation of, "...and wherein the substance is analyzed by contacting the substance with at least one reactant bound to at least a portion of the integral molded part" does not provide any sort of analysis. Such a step only amounts to a step of "contacting" the substance with at least one reactant bound to at least a portion of the integral molded part. The claim does not provide any sort of analysis after such contacting is done and further, does not even provide that the reactant is one that reacts in any sort of manner with the substance. Additionally, as discussed above dependent claims 15 and 16 are maintained as unclear for not reciting the steps involved so as to identify and quantify the analyte (cl. 15), and then further determine a specific concentration of the analyte (cl. 16).

**Additionally, newly added claim 19** is rejected under 35 USC 112, 2<sup>nd</sup> paragraph as similarly previously applied to now-cancelled claim 17. What steps are involved in the preparation so as to enrich, deplete or modify an analyte (cl. 19), and

further, specifically remove at least one of a phosphate, sugar, or fatty acid moiety from the sample (cl. 18)?

Applicant's specification does not provide a clear or distinct description for the processes as claimed in claims 14-16, 18, and 19 and only generally discusses uses in paragraph [0040] of the pre-grant publication US 2006/0275176.

**With regards to claims 1-10, 14, and 17** rejected under 35 USC 102(b) as being anticipated by Shukla, Applicant traverses the rejection. Applicant argues that Shukla does not disclose an integral molded part as Applicant's claims require. Applicant argues that Applicants define "integral" as "the molded part consists of one chemically unitary starting material". Examiner argues that this is not a conventional definition of "integral", and "integral molded part" is conventionally directed toward one or more parts that together constitute a whole. Examiner further argues that claim 1 does not recite that the at least one surface region of the apparatus is made of the same chemical material as the plastic material. Examiner asserts that Shukla discloses an integral molded part of a plastic material with particles of a separation medium 4 (open-pore three-dimensional network) where such separation medium defines the surface region in the apparatus. Examiner asserts that Shukla thereby discloses such an integral molded part as the open-pore three dimensional network is integral with the plastic tube.

A new grounds of rejection has been applied over **claim 19** under 35 USC 102(b) over Shukla in view of Applicant's newly adding the claim to the application.



Examiner also adds the drawings have been objected to for not showing several claimed elements. Examiner asserts that much of the drawings are un-labeled for the claimed structural pieces of the apparatus, and such pieces must be shown/labeled in the drawings.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797